State of Connecticut
Department of Public Health
Division of Health Systems Regulation

In Re: Norwalk Hospital Association d/b/a Norwalk Hospital, Inc.
24 Stevens Street
Norwalk, CT 06856

CONSENT AGREEMENT

WHEREAS, Norwalk Hospital Association, CT., (hereinafter the "Licensee"), has been issued License No. 0053 to operate a General Hospital (hereinafter the "Facility") under Connecticut General Statutes Section 19a-490, by the Department of Public Health (hereinafter the "Department"); and

WHEREAS, the Department's Division of Health Systems Regulation conducted unannounced inspections at the Facility commencing December 18, 2003 and concluding May 20, 2004 for the purposes of conducting multiple investigations; and

WHEREAS, during the course of the aforementioned inspections violations of the Regulations of Connecticut State Agencies were identified in a violation letter dated June 9, 2004 (Exhibit A); and

WHEREAS, a conference call regarding the June 9, 2004 violation letter was held between the Department and the Licensee on June 17, 2004; and

WHEREAS, the Licensee while not admitting to any wrongdoing, is willing to enter into this Consent Agreement and agrees to the conditions set forth herein.

NOW THEREFORE, the Division of Health Systems Regulation of the Department of Public Health of the State of Connecticut, acting herein by and through Marianne Horn, its Director, and the Licensee, acting herein by Geoffrey F. Cole, its President, Chief Executive Officer and Administrator, hereby stipulate and agree as follows:

1. The Licensee shall within thirty (30) days of the execution of this Consent Agreement effect a contract with an established Medical Management Consultant Firm (MMCF) that has expertise in professional and medical health care services. Said MMCF shall be contracted to review professional and hospital services and systems including but not limited to:
   a. The issues identified in Exhibit A of this document.
   b. Review of professional and institution mechanisms for sharing patient information when multiple disciplines are involved in the care of a patient (e.g. information sharing, coordination of services, interdisciplinary care planning).
   c. Review of policies/procedures regarding the Anesthesia and Surgery Departments, delineation of responsibilities, assessments and communication systems for exchange of information between professionals and surgical staff.
   d. Review of surgical and anesthesia services via observations, interviews and reviews of applicable policies and procedures leading to an analysis of the process for the development of an integrated plan of care for the delivery of pre-operative, operative and immediate post operative periods including, but not limited to consideration of medical/surgical conditions which may impact the procedure and/or delivery of anesthesia, goals for parameters of vital signs, utilization of monitoring equipment, patient assessments and documentation of said assessments, oxygen saturation levels, administration of medication and tracking of items/instruments utilized during surgery.
   e. Review of the implementation of patient care policies and procedures throughout the Facility and identification of deviations from said policies and procedures including recommendations for modification of processes.

f. Analysis of incidents in the Anesthesia and Surgery Departments and/or the systems which have a potential to impact quality of care and services.

g. Review of Facility systems inclusive of strengths, weaknesses and recommendations to improve systems.

h. Review of the Facility's Quality Assurance and Improvement Program with emphasis on its ability to identify and respond to system failures.

i. Review of laboratory processes for acceptance and processing of specimens.

j. Review of Pharmacy Services and mechanisms to address the safe and proper dispensing of drugs/biologicals.

k. Review of nursing services with emphasis on the delivery of care and services and documentation of intervention and treatments.

l. Review of maintenance and monitoring policies and procedures for equipment.

m. Review of policies/procedures for informed consent, histories/physicals prior to surgery, implementation of physician orders and accountability for surgical equipment.

n. Review of Emergency Department policies/procedures and practices relative to patient evaluations by physicians and discharge process.

o. Review of the supervision of histopathology laboratory staff regarding processing and testing of tissue specimens and remediation of staff who fail to adhere to the relevant policies and procedures.

2. The MMCF and the Facility shall formalize through a written contract the requirements of this document inclusive of time frames for the initial evaluation, number and credentials of individuals conducting the review, time frames for the analysis and development of recommendations. Said contract shall also specify that the MMCF shall return to the Facility six (6) months after the issuance of its initial report to review the Facility's implementation and monitoring of recommendations. The MMCF shall have thirty (30) days after the completion of said initial onsite review and thirty (30) days after the follow-up review to develop reports and provide copies to the Licensee and

Department. Neither party shall be provided with the opportunity to review the draft reports and both parties shall receive copies of the documents simultaneously.

3. The MMCF shall prepare a report which shall be provided to the Department and the Licensee. Said report shall identify methods utilized for the analysis, areas reviewed and process, findings and recommendations.
4. The Department shall approve the MMCF selected by the Licensee prior to contracting with and/or approving the MMCF.
5. The Licensee shall provide the Department with a time frame for implementation of the MMCF recommendations, within thirty (30) days of receipt of the report.
6. The Licensee shall within sixty (60) days of the execution of this Consent Agreement, in-service histopathology laboratory personnel regarding policies and procedures relating to tissue specimen identification and integrity. Any newly hired histopathology laboratory employees shall review above policies and procedures.
7. The Licensee shall within sixty (60) days of the execution of this Consent Agreement, review and revise, as applicable, the Quality Assurance Program to address the issues identified in Exhibit A.
8. The Licensee shall review, revise and/or develop policies and procedures relative to patient care and services including, the Histopathology Laboratory, Pharmacy Services, Anesthesia, Emergency Department and Surgical Services to identify all situations which have a potential for risk or harm (e.g. tissue specimen processing, supervision of medications and/or instruments and/or laboratory testing, patient assessments, communication between providers of services).
9. The Licensee shall establish a mechanism and program whereby Facility established systems are reviewed on a continuous bases. Said program shall have dedicated staff and resources. Components of the program shall include, but not be limited to:
    a. Establishment of protocols for monitoring inclusive of direct observations and remediation of staff who do not perform duties in accordance with Facility policies/procedures;

b. Ongoing monitoring of systems;

c. Establishment of educational programs to address systems implementation and maintenance.

10. Any records maintained in accordance with any state or federal law or regulation or as required by this Consent Agreement shall be made available to the Department upon request provided, however, peer review materials shall be confidential and not subject to public disclosure as provided by Connecticut General Statutes Section 19a-17b.

11. The Licensee shall designate an RN Shift Administrator, on all shifts who has responsibility for supervision of nursing and ancillary patient care on all clinical units including the assessment of patients, care planning and the care provided by staff. The RN Shift Administrator shall evaluate staff competence, maintain a record of any patient related issue(s) or problem(s) identified on his or her shift and subsequent action taken to resolve the problem(s). Said documents shall be available to the Department and shall be retained for a period of three (3) years.

12. Each RN Shift Administrator shall be provided with:

a. A job description which clearly identifies his/her day-to-day duties and responsibilities;

b. Training programs which clearly delineate each RN Shift Administrator responsibilities and duties in relation to the hospital's policies and procedures for patient and staff observations, interventions, staff remediation, changes in patient condition, and clinical record documentation;

c. Supervision (including reasonable on-site supervision as described below) and monitoring by a representative of the hospital administrative staff, (e.g. Vice President for Patient Care Services) to ensure the RN Shift Administrator is functioning in accordance with this Consent Agreement and state and federal requirements. Said administrative supervision and oversight shall be provided on all three (3) shifts on an irregular schedule of visits; the scheduling and frequency of these visits shall be at the discretion of the responsible administrator. Records of

such administrative visits and supervision shall be retained for the Department's review.

13. The RN Shift Administrator shall be responsible for ensuring through dialogue with unit staff, observation of patient care and medical record review that care is provided to patients by all caregivers in accordance with individual assessments and comprehensive care plans.
14. Within sixty (60) days of the execution of this Consent Agreement, the Licensee shall review and revise, as applicable, policies and procedures relative to:
    a. Medication administration, inclusive of calculation procedures;
    b. Individualized care planning process;
    c. Preventative skin care and monitoring of patients with impaired skin integrity.
    d. Fall risk assessments, pain assessments, neurological assessments;
    e. Laboratory ordering system;
    f. Utilization of defibrillation equipment;
    g. Gastrostomy care;
    h. Interagency referral forms.
15. Implementation of the requirements of paragraph #14 shall be reviewed and evaluated by the MMCF.
16. The Facility shall designate one individual who shall assume the overall responsibility for full implementation of this Consent Agreement. The Department shall be notified as to the identity of this person within seven (7) days of the effective date of this Consent Agreement. A report regarding facility compliance with this Consent Agreement shall be forwarded to the Department on a monthly basis for the first six (6) months and every three (3) months thereafter, by the individual identified by the Facility.
17. The Licensee agrees to pay the Department fifty thousand dollars ($50,000.00), which shall be payable by certified check to the Treasurer of the State of Connecticut and shall be posted to the Department within two (2) weeks of the effective date of this

Agreement. Said check shall be directed to Ann Marie Montemerlo, Supervising Nurse Consultant at the address identified below.

18. Reports and minutes required by this document shall be sent to:

Ann Marie Montemerlo, R.N.
Supervising Nurse Consultant
Department of Public Health
Division of Health Systems Regulation
410 Capitol Avenue, MS #12HSR
P.O. Box 340308,
Hartford, CT 06134-0308

19. All parties agree that this Consent Agreement is an order of the Department with all of the rights and obligations pertaining thereto and attendant thereon. Nothing herein shall be construed as limiting the Department's available legal remedies against the Licensee for violations of this Consent Agreement or of any statutory or regulatory requirements, which may be sought in lieu of or in addition to the methods of relief listed above, or any other administrative and judicial relief provided by law. This Consent Agreement may be admitted by the Department as evidence in any proceeding between the Department and the Licensee in which compliance with its terms is at issue. The Licensee retains all of its rights under applicable law.
20. The execution of this document has no bearing on any criminal liability without the written consent of the Director of the MFCU or the Bureau Chief of the DCJ's Statewide Prosecution Bureau provided, however, the Licensee denies there is any criminal liability.
21. The terms of this Consent Agreement shall remain in effect for a period of two (2) years from the effective date of this document.

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IN WITNESS WHEREOF, the parties hereto have caused this Consent Agreement to be executed by their respective officers and officials, which Consent Agreement is to be effective as of the later of the two dates noted below.

NORWALK HOSPITAL ASSOCIATION OF NORWALK, CT.

11/08/04
Date

By: _____
Geoffrey F. Cole, President, Chief Executive Officer and Administrator

State of Connecticut)
County of FAIRFIELD ss Norwalk Nov. 8, 2004

Personally appeared the above named GEOFFREY F. COLE and made oath to the truth of the statements contained herein.

My Commission Expires: 3/31/06

_____
Notary Public [✓]
Justice of the Peace [ ]
Town Clerk [ ]
Commissioner of the Superior Court [ ]

STATE OF CONNECTICUT,
DEPARTMENT OF PUBLIC HEALTH

11/09/04
Date

By: _____
Marianne Horn, R.N., J.D., Director
Division of Health Systems Regulation

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

June 9, 2004

David W. Osborne, President, CEO and Administrator
Norwalk Hospital, Inc.
24 Stevens Street
Norwalk, CT 06856

Dear Mr. Osborne:

This is an amended edition of the violation letter originally dated June 4, 2004

Unannounced visits were made to Norwalk Hospital Inc. on December 18, 23, 2003 and April 6, 7, 8, 12, 29 and 30, 2004 by representatives of the Division of Health Systems Regulation for the purpose of conducting multiple investigations with additional information received through May 20, 2004.

Attached are the violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which were noted during the course of the visits.

An office conference has been scheduled for June 17, 2004 at 10:00 AM in the Division of Health Systems Regulation Conference Room, Department of Public Health, 410 Capitol Avenue, Second Floor, Room E, Hartford, Connecticut.

Please prepare a written Plan of Correction for the above mentioned violations to be presented at this conference.

Each violation must be addressed with a prospective Plan of Correction which includes the following components:

1. Measures to prevent the recurrence of the identified violation, (e.g., policy/procedure, inservice program, repairs, etc.).

2. Date corrective measure will be effected.

3. Identify the staff member, by title, who has been designated the responsibility for monitoring the individual plan of correction submitted for each violation.

If there are any questions, please do not hesitate to contact this office.

Respectfully,

Joan Leavitt

Joan Leavitt, R.N., M.S.
Public Health Services Manager
Division of Health Systems Regulation

Judy McDonald

Judy McDonald, RN
Supervising Nurse Consultant
Division of Health Systems Regulation

JDL:JFM:zbj

cc: Director of Nurses
Medical Director
President
vlnorwalk.doc
#2003-864, #2003-1243, #2003-754, #2003-1326, #2003-1324, #2003-1203
#2003-956, #2003-1320, #2003-1244, #2003-1325, #2003-753, #2003-938
#2004-122, CT#2598, CT#2819, CT#2728, CT#2731, CT2730, #CT2672

Phone:
Telephone Device for the Deaf: (860) 509-7191
410 Capitol Avenue - MS #_____
P.O. Box 340308 Hartford, CT 06134

DATES OF VISIT: December 18 and 23, 2003; April 6, 8, 12, 29 and 30, 2004.

THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

#CT1891, #CT1512, CT#1371, CT#1496, CT#2374, CT#2036, [illegible]
#2003-753, CT#1994, CT#1496, CT#2036, CT#1891, CT1512, [illegible]

1. Based on a review of the medical record, review of facility medical staff by-laws, review credentialing file, and interviews, the facility failed to ensure that one Physician Assistant was appropriately credentialed with privileges defined for practice.
    a. Patient #3 underwent a laparoscopic Roux en Y Gastric bypass and lysis of adhesions due to morbid obesity on 1/12/04. An operative note written on 1/12/04 at 3:30 PM identified the patient returned to the OR for a laparoscopic removal of an EEA trochar. MD #36 was assisted on both cases by PA #2. A review of PA #2's credentialing file identified she had never been credentialed to practice in the facility. A review of the facility's Medical Staff Bylaws, Policies, and Procedures identified the Allied Health Professionals Review Committee must review all relevant information about the applicant and determine whether the applicant has satisfied all of the qualifications for the scope of practice requested, shall prepare a written report of its findings and recommendations, shall submit it to the Chief Executive Officer who will forward it to the Executive Committee and Board for information and action on the requested scope of practice. During an interview the Medical Staff Coordinator stated because the PA was a previous employee the Human Resources Department processed her without obtaining the appropriate credentialing information. Subsequent to this surveyor inquiry the facility suspended PA #2 from practice until proper credentialing was completed.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (1)(B) and/or (c) Medical Staff (2)(A) and/or (4)(A) and/or (i) General (7).

2. Based on clinical record reviews and staff interviews, the facility failed to ensure that quality medical care was provided to Patients #26 and #70 and include the following:
    a. Patient #26 had diagnoses that included pneumonia. Observations on 4/6/04 on the 6E nursing unit identified that Patient #26 was receiving Peripheral Parenteral Nutritional (PPN). Review of laboratory values used to monitor the patient's nutritional status included a pre albumin level dated 3/30/04 reported at 9.5 (Normal 60-125). Review of the medical record identified a nutrition consult dated 4/2/04 that requested the patient's pre albumin be rechecked. On 4/6/04, the record identified an additional nutritional consult that again requested that the pre

albumin be rechecked. Interview with the Manager of Nutrition and Services on 4/7/04 identified that although the dietician who completed consult requested the blood work, it was the physician's responsibility to write the orders for implementation. Interview with the 6E Unit Manager on 4/7/04 identified that MD #24 identified that he thought that the dietician could write the orders for the blood work. Subsequent to surveyor inquiry, a pre albumin level was drawn on 4/8/04 and reported as 14.2.

b. Patient #70 was admitted from a nursing home on 3/31/04 with diagnoses that included pneumonia with mental status changes. Review of the interagency referral form from the nursing home identified medication orders that included an Oxytrol (oxybutynin) patch (prescribed for bladder control issues) 3.9 milligrams (mg.) to be worn twenty four hours a day, to be changed twice weekly, and that the patch was due to be changed on 4/2/04. Review of MD #25's handwritten orders dated 4/1/04 identified that the Oxytrol patch was to be discontinued and an order was written for a Duragesic patch (a narcotic analgesic prescribed for pain control) 50 micrograms (mcg.) to be administered beginning 4/2/04. Interview with MD #25 on 4/29/04 identified that when she discovered that Oxytrol was not available, she called an unidentified pharmacist for a substitute medication. MD #25 further stated that when she called the pharmacist for a substitution for the Oxytrol patch, she had thought "Oxytrol was an Opioid." At the time of the conversation on 4/1/04 with the pharmacist, she believed the direction from the pharmacist was appropriate.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (c) Medical Staff (4)(D) and/or (i) General (7).

3. Based on a review of the medical record, review of facility Medical Staff Bylaws, and interviews, the facility failed to ensure for Patient #14 that a discharge summary addendum was done.

   a. Patient #14 was admitted to the facility on 6/24/03 due to COPD, bullous emphysema, atrial fibrillation and GI bleed. A review of the medical record on 4/8/04 identified a discharge summary dated 6/26/03 that identified the patient was discharged to a nursing home. The patient suffered a change in condition, was not discharged and expired in the facility on 7/5/03. Documentation was lacking that an addendum to the discharge summary was completed. A review of the facility's Medical Staff Bylaws identified a discharge summary must be written within 14 days of the patient's discharge.

THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

During an interview [illegible] Administrative Director of Health Information Management (HIM) [illegible] the discharge summary required an addendum and there was none.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (c) Medical Staff (2) and/or (4)(D) and/or (d) Medical Records (3) and/or (i) General (7).

4. Based on clinical record reviews, staff interviews, review of facility policies and procedures, the facility to ensure physician orders were followed (Patients #11 and #12) and/or that assessments were performed (Patients #4, #7, #13, #70 and #71) and/or that facility policies and procedures were implemented for Patient #15 and #18. The findings include the following:
   a. Patient #12's diagnoses included chronic renal failure, which required hemodialysis, diabetes, history of myocardial infarction, and history of bleeding from operative sites. Review of the medical record identified that the patient underwent a creation of an AV fistula and change of a Perm-Cath on 10/17/03. The patient was admitted for observation due to a soaked and bloody AV fistula dressings on 10/17/03. Further review of the medical record identified that the patient soaked through the AV fistula dressing site on 10/17/03 while in the recovery room. The patient's blood pressure dropped to 85/41 (baseline was 103/45 to 153/98) and the patient complained of feeling shaky. The patient was treated with intravenous fluids. The labs dated 10/18/03 identified hemoglobin 9.2 (was 10.5 on 10/16/03) and hematocrit 27.9 (was 31.4 on 10/16/03). The doctor's orders dated 10/18/03 directed a complete blood count (including hemoglobin and hematocrit) for 10/19/03. Review of the medical record lacked documentation that a complete blood count was done and the patient was discharged on 10/19/03. The patient was readmitted on 10/20/03 with an acute myocardial infarction, a hemoglobin of 7.6 and hematocrit of 22.9. Review of the medical record and interview with the Nurse Manager identified that the secretary noted that the order for the lab work was entered into order system and the nurse (RN #7) signed that the orders were verified, but the labs were not put into the order system. Review of the Order Transcription Policy directs that the Registered Nurse (RN) is responsible for the transcription of doctor's orders. The RN shall verify the orders transcribed by the unit secretary.
   b. Patient #15's diagnoses included cardiomyopathy, cardiac arrest and aspiration pneumonia. On 4/20/03, the patient went into cardiac arrest and was coded. During the code, the patient did not respond to the first five-defibrillation shocks.

THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

It was then noted that the defibrillation pads were not connected to the monitor. The pads and cable were connected, the code was resumed, and the patient was resuscitated. The nurse (RN #6) failed to ensure that the pads were connected to the monitor when the pads were applied. Interview with the Intensive Care Unit Nurse Manager identified that the nurse who applied the defibrillation pads should ensure that they are connected to the monitor.

c. Patient #7, 80 years old, was admitted to the endoscopy unit on 10/29/03 with diagnoses of Barrett's esophagus, osteoporosis, osteoarthritis, kyphoscoliosis, and bilateral hip replacements. Interview with RN #21 identified that she escorted the patient into an examination room, gave her hospital clothing, and instructed her to change. The nurse returned to find Patient #7 on the floor. The patient stated that the only place to sit and change was a rolling stool and when she sat, it rolled out from under her. The patient was assisted to the stretcher/bed, examined, and given an ice pack for complaints of back pain. The patient was discharged following the completion of a panendoscopy. Patient #7 was re-admitted to the hospital on 10/31/03 and diagnosed with a contusion and muscle strain of the left back and iliac area. Interview with RN #21 identified that she attempted to assess the patient but the patient refused, stating "get me up." RN #21 stated she did not document the fall, subsequent assessments, or treatments rendered. Interview with the nursing supervisor identified that because the patient did not want to stay on the floor, they assisted her to the bed and then conducted an assessment. Also that per policy, the patient should have been assessed prior to being moved.

d. Patient #11 had an upper endoscopy performed on 9/4/03 that identified a bleeding duodenal ulcer. Review of an operative report dated 9/11/03 identified that a jejunostomy tube was inserted for enteral feedings and gastrostomy tube (g-tube) was inserted for drainage of gastric contents. Review of a nurse's note dated 11/16/03 with RN #12 identified that the patient had vomited large amounts of green bile, had an oxygen saturation of 50% on 2 liters of oxygen, required aggressive suctioning and a respiratory treatment. Subsequently, the oxygen saturations increased to 92-93% on 100% non-rebreather oxygen, the patient was evaluated by a physician and transferred to the ICU. RN #12 stated that the g-tube was discovered to be clamped off by the stop cock and when unclamped, drained approximately 450 cc of green bile. RN #12 stated during interview that it was uncertain how the g-tube became clamped. Review of the ICU admission note dated 11/16/03 identified that the patient had an acute episode of emesis, became hypoxic, required Continuous Positive Airway Pressure (CPAP) and aggressive pulmonary toilet. Chest x-ray identified a right lower lobe infiltrate and left lower

THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

lobe p[illegible] and or infiltrate with a diagnosis of chemical as[illegible] pneumonitis [illegible].

e. Patient #4's diagnoses included atrial fibrillation. Nurses' notes dated 6/30/03 at 11:30 p.m. identified that the patient was found unresponsive on the floor and sustained a 4 to 5 centimeter laceration of the head requiring staples. The nursing care record dated 6/30/03 on the 11:00 p.m. to 7:00 a.m. shift lacked frequent neurological assessments and subsequent to the fall, the patient was confused and disoriented. Review of the CT scan with MD #11, a radiologist, identified a right parietal cephalohematoma (without evidence of intracranial hemorrhage). MD #11 stated that follow-up treatment would depend upon how the resident presented clinically. The clinical record identified that neurological assessments were completed initially on 6/30/03 at 12:00 a.m. and then on 7/1/03 at 4:00 a.m., 8:00 a.m., 11:00 a.m. and then at 4:00 p.m. RN #8 stated that there is not a protocol for head injury and neurological assessments. The Director of Quality Management stated that neurological assessments are based on nursing judgment or physician's order.

f. Although the facility had a policy to monitor pain/sedation assessments every four hours for patients that received Patient Controlled Anesthesia (PCA), the facility lacked a policy to specifically address the frequency of pain/sedation assessments for those patients that received continuous infusion analgesics after the initial institution of the medication and/or when there was a change in dosage. Patient #13's pain level was assessed at "0" at 5:00 PM on 11/10/03. The record lacked documentation to reflect that any subsequent pain/sedation assessments were provided until 2:00 AM on 11/12/03 when Patient #13 was observed to be obtunded. Interview with RN #19 on 4/6/04 identified that she was not aware at the time the MSO4 infusion bag was hung by RN #16 but she knew the patient was on a low dose of MSO4 and that the bag should have lasted the entire night. Although RN #19 identified that she usually makes rounds every hour on her assigned patients, the unit was very busy that night and that it may have distracted her from her usual routine. RN #19 identified that she heard Patient #13's pump alarm sounding at approximately 2:00 PM and went to check on the patient. RN #19 observed that the pump was set to deliver the MSO4 at a rate of 6 milligrams (mg.) per hours instead of 0.6 mg. per hour, the entire bag had infused, and that Patient #13 was very sedated. Review of the physician's progress note dated 11/11/03 at 3:00 PM identified that Patient #13 had inadvertently received ten times the prescribed dose of MSO4, a total of 500 mg. over a five and one half

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hour time period and had experienced an unintended state for several hours as a result.

g. Patient #70 was admitted from a nursing home on 3/31/04 with diagnosis that included pneumonia with mental status changes. Patient #70 was discharged back to the nursing home on 4/3/04. Review of the discharge interagency referral form dated 4/3/04 and signed by MD #25 identified instructions for Patient #70's discharge medications that included an order for an Oxytrol patch 3.9 mg. to be applied. The discharge instructions failed to identify a date or time that the Oxytrol patch was administered. The discharge instructions lacked documentation that a Duragesic Patch 50 mcg. had been applied at 8:00 AM on 4/2/04 or any additional orders and/or instructions for use of the patch. Patient #70 was transferred back to the hospital's Emergency Department in cardiac arrest on 4/3/04 at 11:50 PM. Despite efforts to resuscitate the patient, Patient #70 expired at 12:00 midnight on 4/4/04. Review of the facility policy for discharge education and instructions identified that the completed form will provide documentation of medications and directions for use in order to document the discharge plan and instructions to the patient or the person responsible for the patient at the time of discharge.

h. Patient #71 had multiple diagnoses that included pneumonia, a history of malnutrition, alcohol (ETOH) and drug abuse, and diabetes and was admitted to the facility on 12/14/03. The medical record identified that Patient #71 developed multiple Stage II ulcers of the coccyx, inner right thigh, the mid back, and a necrotic area at the occipital area (the back of the head) at various intervals during the prolonged hospital admission.

   i. While the medical record identified some revisions to address areas that developed and included increased repositioning, a gel pad for the patient's head ordered on 2/14/04, and a Clinitron bed (specialized bed) on 3/1/04, the record lacked documentation that the treatments were consistently administered and/or monitored for effectiveness and/or that the plan of care was consistently followed.

   ii. The documentation dated 2/3/04 identified that a "black, necrotic area" was noted at Patient #71's right cheek without measurements of the area. On 2/4/04, the documentation identified that a "linear laceration on the right cheek with minimal necrosis" was noted but lacked documentation of a measurement of the area. Review of the plastic surgery consult dated 2/4/04 identified that Patient #71 had a "full thickness wound to right corner of the mouth extending to the right cheek." Interview with the ICU

THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

Manager on 4/29/04 identified that the p[illegible] wound from the endotracheal tube (ETT) that w[illegible] Manager stated that the respiratory therapists are responsi[illegible]eck placement of the ETT tube during routine ventilator checks. Ti[illegible] Manager stated that there was currently no system in place for documentation that the tube checks were completed. Observation of Patient #71 on 4/29/04 identified the patient had a thick linear scar that extended from the right corner of her mouth to the mid cheek. The area was approximately 3.0 cm. in length.

In addition, review of the medical record lacked consistent documentation of measurements of Patient #71's multiple pressure ulcers in accordance with the facility's policies for prevention and treatment of pressure ulcers. Observations on 4/29/04 at 11:50 AM identified that Patient #71 had an approximate 3.0 centimeter (cm.) uncovered, open, moist wound on the left buttocks, an approximate 6.0 cm. long, thin slit like moist open area at the sacrum, and an approximate 2.0 cm. abrasion at the inner left thigh. An approximate 7.0 cm. thin dried black line across the mid back was observed. Interview with RN #25 identified that the mid back area was "all dried up now." Observation of Patient #71's occipital area identified an approximate 10.0 cm.by 5.0 cm irregular blackened area at the back of the head with an approximate 2.5 cm. circular area of the same blackened material at the upper top side of the larger area. Strands of Patient #71's hair were observed to be matted into the blackened head wound. Interview with RN #25 identified that wound measuring materials were accessible to staff.

Review of facility policy directed that Stage II and greater wounds would be measured at least every five days and as needed and that the documentation would include wound size, depth, color, stage and treatment.

i. Patient #18's diagnoses included back pain and chest pain. The admission assessment dated 3/26/04 lacked documentation that a fall risk assessment was completed. On 4/2/04, the patient was transferred to another nursing unit and was assessed to be at extremely high risk to fall. The clinical record identified that Patient #18's risk to fall was assessed between high and extremely high risk to fall between 4/2/04 and 4/8/04. Observation of Patient #18 on 4/6/04 with the 7th floor Resource Manager identified that Resident #18 did not have a green I.D. bracelet on and did not utilize a bed alarm. According to the fall prevention

THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

protocol. patient who are assessed to be at high risk to fall wear a green identification bracelet and will have a bed alarm is initiated.

j. Patient #4's diagnoses included atrial fibrillation. The nursing admission assessment dated 6/26/03 identified that the patient was alert and oriented and at low risk to fall. Nurses' notes dated 6/30/03 identified that the patient was found unresponsive on the floor and had a 4 to 5 centimeter laceration of the head requiring staples. The facility investigation identified that Patient #4 wore a green I.D. bracelet, which according to facility policy, is utilized for a patient that is assessed to be at high risk to fall. Review of the clinical record with RN #4 identified that it lacked documentation of the change in the patient's fall risk and/or that Patient #4's fall risk was re-assessed after the fall on 6/30/04. RN #4 stated that there was no place on the flow sheet to identify that the patient's fall risk increased.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Service (1) and/or (i) General (7).

5. Based on clinical record reviews and staff interviews, the facility failed to develop comprehensive nursing care plans and/or revise nursing care plans for Patients #5, #6, #13, #14 and #71 and include the following:

   a. Patient #5's diagnoses included pneumonia and atrial fibrillation. The nursing admission assessment dated 11/1/03 identified that the patient was at low risk to fall and was alert. Review of the clinical record identified that the patient's mental status varied from alert and oriented to vague and forgetful. Nurses' notes dated 11/3/03 on the 11:00 p.m. to 7:00 a.m. shift (into 11/4/03) identified that Patient #5 tried to climb out of bed at 5:00 a.m. and had periods of confusion. Nurses' notes dated 11/4/03 at 10:30 a.m. identified that the patient was found on the floor and a left humeral surgical neck fracture was diagnosed. Review of the clinical record with RN #8 identified that after Patient #5 attempted to climb out of bed, the patient was not reassessed nor was the care plan revised to address the patient's safety. Facility policy identified that patients will be assessed for their risk to fall throughout the hospitalization as their condition warrants and a note will be written when a fall risk assessment indicates a change.

   b. Patient #6 was admitted to the facility due to pneumonia and a urinary tract infection. A review of Patient #6's medical record identified the patient had a cast on her right ankle as the result of a preadmission fracture, had a healing

ulcer on the left lower leg and multiple skin tears on both forearms, was oxygen dependent and required the use of a BiPap machine at night, had repeated episodes of agitation due to hypoxia especially at night, suffered a skin tear and de-gloving injury to the right hand, and required restraints to keep the patient from removing her oxygen and de-saturating. A review of the patient's care plan failed to identify any problems and/or interventions and/or goals for these issues. Interview and review of the care plan with the 7 West Patient Care Manager identified the above mentioned issues were not part of the care plan.

c. Patient #13 had diagnoses that included Stage IV Bladder Carcinoma. Review of the physician's order sheet dated 11/9/03 identified orders that included MSO4 500 mg. in 50 cc of Dextrose and water to run at 0.5 cc 5mg. per hour. In addition, the order identified that the dosage could be increased by 0.1 cc/1 mg. increments to a maximum of 1.0 cc/10 mg. per hour. Review of the medical record identified that although a plan of care dated 11/10/03 addressed Patient #13's "general pain," the plan of care lacked documentation of a comprehensive plan of interventions that included how frequently pain and/or sedation assessments were to be monitored during the continuous infusion of MSO4 or parameters for increase of the MSO4 dosage as it related to the patient's reported level of pain.

d. Patient #14 was admitted to the facility on 6/24/03 due to COPD, bullous emphysema, atrial fibrillation and GI bleed. A review of the special events record identified at 8:00 p.m. RN #23 identified she gave the patient Oxycontin SR 40 mg at 7:45 p.m. by mistake and notified the physician. The patient was sleepy, had a respiratory rate of 12, Narcan 0.4 mg IV was given at 9:00 PM. The patient was placed on every two hour neuro checks and vital signs, and had charcoal 30 grams given at 9:30 p.m. A review of the flow record identified documentation was lacking for neuro checks and vital signs at 6 and 8 a.m. on 6/29/03. A review of a pulmonary consult dated 6/29/03 identified the patient was given Oxycontin in error which caused a decreased respiratory rate, blood pressure, and lethargy secondary to increased CO2 retention in the patient who was a chronic retainer. During an interview the Patient Care Manager for 7W stated additional monitoring, interventions, or assessments were needed due to the administration of the medication and were not on the patient's care plan.

e. Patient #71 had multiple diagnoses that included pneumonia, a history of malnutrition, alcohol (ETOH) and drug abuse and diabetes. Review of the

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admission assessment dated 12/14/03 identified Patient #71 [illegible]derate risk for pressure ulcers. Review of the medical record lacked [illegible]mentation of a comprehensive plan of care with consistent interventions that included assessments and/or frequent repositioning and/or measurable goals to address Patient #71's risk for skin impairment prior to skin breakdown. The record identified that Patient #71 developed multiple Stage II ulcers of the coccyx, inner right thigh, the mid back, and a necrotic area at the occipital area (the back of the head). In addition, review of Patient #71's medical record identified that the patient was intubated for respiratory distress on multiple occasions throughout the prolonged hospital stay. Review of the record identified that Patient #71 was intubated on 1/27/04 after the patient experienced a cardiac arrest. Patient #71 remained intubated for seven days and was extubated on 2/3/04. Review of the medical record lacked documentation to reflect the patient's risk for skin breakdown at the site of the Endotracheal Tube (ETT). The documentation dated 2/3/04 identified that a "black, necrotic area" was noted at the patient's right cheek on the day that the patient was extubated. The ICU Manager stated that the respiratory therapists are responsible to check placement of the ETT tube every twenty four hours during routine ventilator checks. The ICU Manager stated that there was currently no system in place for documentation that the tube skin checks were completed. Review of the facility's policies for prevention and treatment of pressure ulcers identified that an appropriate plan of care would be initiated for those patients identified as at moderate or high risk for skin breakdown.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (e) Nursing Service (1).

6. Based on interviews and record reviews and staff interviews, the facility failed to administer medications according to physician's order for Patients #7, #9, #13, #14 and #17.
    a. Patient #7, 80 years old, was admitted on 10/29/03 for treatment of left back pain. Physician orders dated 11/2/03 identified to administer Percocet 1-2 tablets every 4 hours as needed. Review of Patient #7's medication administration record identified that Percocet 2 tablets were administered on 11/4/03 at 10:20 AM and another 1 tablet at 12:20 PM, two hours later. Interview with the Quality Manager and the Manager of Unit 8 East identified

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that the Percocet administered at 12:20 PM was given in error and should not have been administered within two hours of the 10:20 AM dose.

b. Patient #9 had diagnosis that included intractable vomiting and was identified as alert and oriented. Review of the medical record identified a physician's order dated 10/22/02 for Peripheral Parental Nutrition (PPN) with standard additives but no additional medications. Review of facility documentation identified that Patient #9 inadvertently received a mixture of parental nutrition intended for Patient #8 that included the same standard additives as well as Ranitidine 150 milligrams (mg.). The documentation identified that the error was noted one and one half hours later and that the infusion was discontinued. Interview with RN #7 on 4/7/04 identified that she had been very busy that evening and that she quickly grabbed a TPN bag from the counter of the medication room. RN #7 identified that she must not have checked Patient #9's name band before hanging the TPN but was unable to recall any further details. The record lacked documentation that any additional intervention as a result of the error was necessary. Review of facility policies on medication administration identified that "the five rights" that included administration to the right patient, must be substantiated. In addition, the policy directed that prior to administration of medications, the patient must be identified by their identification bracelet and by speaking their name when appropriate.

c. Patient #13 had diagnosis that included Stage IV Bladder Carcinoma. Review of the physician's order sheet dated 11/9/03 identified orders that included Morphine Sulfate (MSO4) 500 milligrams (mg.) in 50 cubic centimeters (cc.) of Dextrose and water to run at 0.5 cc/ 5 mg. per hour. In addition, the order identified that the dosage could be increased by 0.1 cc./1 mg. increments to a maximum of 1.0 cc/10 mg. per hour. Review of the medical record identified that the rate of the MSO4 infusion was increased to 0.6 cc./6 mg. per hour on 11/10/03. Review of the medical record identified that a new infusion bag containing 500 mg. of MSO4 in 50 cc. of dextrose and water was hung by RN #16 at 5:00 PM on 11/10/03. Review of the medical record identified that at 1:45 AM on 11/11/03, five and one half hours after RN #16 initially hung the infusion bag containing MSO4, RN #19 heard the alarm of patient's delivery pump that was set to deliver the MSO4 solution. The medical record identified that RN #19 observed the setting on Patient #13's pump had been programmed at 6 cc. per hour rather than 0.6 cc. per hour and that the infusion bag was empty. Interview with RN #19 on 4/6/04 identified that she assessed Patient #13, found the patient to be very sedated, and notified the physician. Review

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of the physician's progress note dated [illegible]3 at 3:00 AM identified that Patient #13 had inadvertently received [illegible] times the prescribed dose of MSO4, a total of 500 mg. over a five and one half hour time period. Patient #13 subsequently received fourteen doses of Narcan 0.4 mg. between 8:07 am and 2:10 PM on 11/11/03 before the patient became easily arousable. Review of the discharge summary dated 12/09/03 identified diagnosis that included Iatrogenic morphine excess and that Patient #13 had experienced an obtunded state for "several hours" as a result. The discharge summary further identified that after the inadvertent nursing error.

d. Patient #14 was admitted to the facility on 6/24/03 due to COPD, bullous emphysema, atrial fibrillation and GI bleed. A review of the special events record identified at 8:00 p.m. that RN #23 identified that she gave the patient Oxycontin SR 40 mg at 7:45 p.m. (in error) and notified the physician. The patient was sleepy, had a respiratory rate of 12, Narcan 0.4 mg IV was given at 9 p.m., the patient was placed on every two hour neuro checks and vital signs, and had charcoal 30 grams given at 9:30 p.m. A review of the flow record identified documentation was lacking for neuro checks and vital signs at 6 and 8 a.m. on 6/29/03. A review of the physician orders failed to identify any order for Oxycontin. A review of a pulmonary consult dated 6/29/03 identified the patient was given Oxycontin in error which caused a decreased respiratory rate, blood pressure, and lethargy secondary to increased CO2 retention in the patient who was a chronic retainer. A review of the medication administration record failed to identify any Oxycontin SR given. A review of the facility medication administration policy identified when medication is administered the five rights must be substantiated and medication given documented on the MAR (medication administration record). During an interview RN #23 stated she mistakenly gave Patient #14 Oxycontin SR that was meant for another patient when she put the Oxycontin in Patient #14's medicine cup in error, and additionally did not think to record it on the MAR. During an interview the Patient Care Manager for 7W stated anything on the MAR required a physician order and since there was no order for this medication, it could not be recorded, and that the vital signs and neuro checks were not done in accordance with physician orders.

e. Patient #17 had diagnosis that included Atrial Fibrillation (A-Fib), acute coronary syndrome, a history of lung cancer, Chronic Obstructive Pulmonary Disease (COPD) and was admitted to the facility on 8/8/03 with multiple traumas after a motor vehicle accident. Review of the medical record

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identified that Patient #17 experienced multiple episodes of respiratory failure since admission that required multiple Intensive Care Unit (ICU) admissions, intubations, and a subsequent tracheotomy. Review of Patient #17's Medication Administration Record (MAR) identified that the patient received Xanax 0.125 milligrams (mg.) on 12/26/03 at 5:31 PM and on 12/27/03 at 6:00 AM. Review of the medical record identified that Patient #17 became "very sleepy" and was transferred to the telemetry unit on 12/27/03 at 3:15 PM after the patient developed increased lethargy, a rapid heartbeat and increased respirations. Review of the medical record identified documentation of an allergy to benzodiazepines as of 12/27/03. Review of the medical record identified physician's orders dated 12/28/03 for a single dose of Xanax 0.125 mg. via the patient's feeding tube. Interview with the ICU Manager on 4/8/04 identified that RN #26 administered the Xanax on 12/28/03 despite the 12/27/03 documented allergy to benzodiazepines. The ICU Manager identified that Xanax is available on the unit through the facility's Omnicell medication storage cart and that the nurse may not have equated the Xanax with benzodiazepines when it was administered. On 12/29/03, the progress notes identified that Patient #17 remained sedated due to Xanax. Patient #17 was subsequently transferred back to the ICU on 12/29/03 for a sixth ICU admission since her initial admission date of 8/8/03. Review of the Infectious Disease consult note dated 12/28/03 identified that the consultant believed that the precipitating factor for the event was "sedating drugs causing aspiration from mucous plugging." Patient #17 was observed in the ICU on 4/7/04 and again on 4/29/04 to be alert. The family member of Patient #17 was present and making plans with the facility staff for discharge. In addition, review of Patient #17's medical record identified physician's orders dated 12/28/03 for Xanax 0.125 mg. Although the 12/28/03 order for the one time dose of Xanax did not identify a time, the documentation identified that the last physician order entries previous to the untimed Xanax order were entered at 10:30 PM on 12/28/03 and the orders subsequent to the Xanax order were at 7:00 AM on 12/29/03. Review of the MAR dated 12/28 through 12/29/03 lacked documentation to reflect that the Xanax was administered to Patient #17 between 10:30 PM on 12/28/03 and 7:00 AM on 12/28/03. Interview with the ICU Manager identified that the Xanax was given on 12/28/03 but at the time of the interview, was unable to identify the nurse who had administered the medication. Review of facility policy on charting of medications directed that medications should be charted as they are given. In addition, the policy

directed that if a charting omission occurred, after ascertaining that the medication was given, the medication should be documented.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Service (1) and/or (i) General (7).

7. Based on review of the clinical record, review of facility documentation, and staff interviews for one patient (Patient #5), the facility failed to ensure that a physician's order was obtained for oxygen. The findings include:
    a. Patient #5 was admitted to the facility via the emergency department on 10/31/03 in acute respiratory distress with diagnoses including pneumonia and chronic obstructive pulmonary disease. The nursing admission assessment dated 11/1/03 identified that the patient was utilizing a venti- mask at 50 percent when the patient arrived on the nursing unit. Review of the clinical record dated 11/1/03 to 11/2/03 with RN #8 identified that although oxygen was utilized intermittently, the record lacked a physician's order for the oxygen. RN #8 stated that although Patient #4 was admitted on a venti-mask, the patient was admitted privately and therefore did not have the pre-printed physician order sheet that a house officer would use.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (e) Nursing Service (1) and/or (i) General (7).

8. The facility failed to ensure for Patient #8 that adequate supervision of medication was performed to prevent error. The findings are based on clinical record review and staff interviews and include the following:
    a. Patient # 8 had diagnosis that included diarrhea and failure to thrive. Review of the physician's order sheet dated 10/21/03 identified orders for Total Parental Nutrition (TPN) that included the addition of 150 milligrams (mg.) per day of Ranitidine to be added to the TPN mixture. Interview with Pharmacist #6 on 4/7/04 identified that he was responsible for input into the computer on 10/21/03 that generated TPN labels that would be utilized by the Pharmacy Technician in preparing the TPN. Pharmacist #6 identified that he had inadvertently entered 150 mg. of insulin rather than the Ranitidine as prescribed. Pharmacist #6 identified that although he was called that evening by the pharmacist on duty to verify the addition of the insulin to Patient #8's TPN bag, he confused Patient #8 with another patient, Patient # 72. Pharmacist #6 identified that he told the

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pharmacist that he had already taken care of the issue and that it was okay to use the prepared TPN. Pharmacist #6 identified that when he checked Patient #8's laboratory values on the morning of 10/22/03, he noted that the patient's blood sugar was very low, realized the error, and called the unit to stop the TPN infusion. Interview with the Director of the Pharmacy on 4/7/04 identified that all TPN infusions are hung at 8:00 PM. Review of the medical record identified that the infusion containing 150 mg. of insulin was hung infused into Patient #8 from 8:00 PM on 10/21/03 until 9:30 AM on 10/22/03, a total of thirteen and one half hours. Review of the medical record identified that at 12:00 AM on 10/22/03, Patient #8's blood sugar was 35 (normal 65-125). The physician was notified and three ampules of Dextrose intravenously (IV) and Glucogan 1 mg. subcutaneously were administered in addition to increased IV fluids. Patient #8's blood sugar was monitored hourly throughout the night and ranged between 35 and 69, with one exception at 5:00 AM when the blood sugar was reported at 95. Review of the progress note dated 10/22/03 at 9:30 AM identified that the error of the addition of insulin to Patient #8's TPN infusion was discovered and the infusion was discontinued. Patient #8's blood sugar continued to be monitored and was reported at 144 at 2:00 PM on 10/22/03.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1) and/or (g) Pharmacy (2) and/or (i) General (7).

9. Based on observation, the facility failed to ensure that the necessary preventative maintenance and testing of equipment was performed based on hospital policy and include the following:
    a. During a tour of the pharmacy on 4/6/04, the preventive maintenance, testing and/or cleaning of the Baker and NuAire hoods were found to be last completed eight and one half months ago on 7/23/03. Interview with the Director of the Pharmacy on 4/6/04 identified that the hospital's policy included checks of the hoods every six months.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (3) and/or (i) General (7).

10. Based on record review of policies and procedures, quality assurance documentation and staff interviews, the laboratory failed to meet the requirements of Histopathology for

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specimen identification and integrity, specimen processing and documentation of cryostat maintenance and/or the laboratory failed to provide specimen-processing procedures adequate enough to ensure specimen identification and integrity when an unknown source of contamination was found in a histopathology specimen on Patient #10 and/or failed to document cryostat maintenance before April 2004. The findings include:

a. Based on a review of a patient test report and interview with the director and the medical student, it was determined that specimen identification and integrity procedures were not adequately performed on August 7, 2003, when a testicular histology specimen was contaminated with lung tissue from another patient. The cause of contamination is unknown, however, specimen-processing procedures were not adequate enough to ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt through completion of the testing and reporting of results. Findings include:
   i. The director stated that cancer cells were present on the frozen section performed during surgery, however, the results were probably unreliable because the pathologists were unable to verify the presence of carcinoma in other sections of tissue.
   ii. The patient test report indicated in part: "Without clear evidence of other foci of carcinoma, it is felt that the carcinoma seen on the frozen sections is a probable contaminant from another case." Subsequently, Patient #10's left testicle was removed due to a contaminated tissue slide. Interview with the Pathologist, MD #8, identified that there was probably contamination from a previous case during processing of Patient #10's tissue specimen.

b. Based on a review of a patient test report and interview with the laboratory director and a pathology student, it was determined that the laboratory's procedure for histopathology specimen processing was not adequate. Findings include that a contamination error occurred during the cutting and mounting of a histopathology frozen section, resulting in unreliable test results. Interview with the student indicated that supervision was adequate, because the pathologist was overseeing and directing the processing of that specimen. However, the test report indicates that the result was unreliable because of probable contamination. Subsequently, Patient #10's left testicle was removed due to a contaminated tissue slide. Interview with the Pathologist, MD #8, identified that there was probably contamination from a previous case during processing of Patient #10's tissue specimen.

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c. Based on a review of quality control records and interview with the director, it was determined that maintenance was not performed on August 7, 2003, when frozen sections were prepared for examination. The cause of contamination is unknown, however, instrument maintenance was not documented daily as recommended by the manufacturer of the cryostat. Subsequently, Patient #10's left testicle was removed due to a contaminated tissue slide. Interview with the Pathologist, MD #8, identified that there was probably contamination from a previous case during processing of Patient #10's tissue specimen. As a generally accepted rule, if maintenance was not documented, then it was not performed. The cryostat operator's manual indicates that cleaning must be performed on each day of use. The quality control record indicates that the laboratory began documenting cryostat cleaning on April 1, 2004. The director stated that cleaning was performed but not documented on August 7, 2003, when specimen contamination occurred. Subsequently, Patient #10's testicle was removed due to contaminated tissue slide.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (f) Diagnostic and therapeutic facilities and/or (i) General (7).

11. Based on a review of facility documentation, physician credentialing files, and interviews, the facility failed to ensure current surgical privilege lists were on file in the OR.

a. During a review of the surgical privileges book in the OR it was identified that the multiple privilege lists on file dated back to 1999. A review of the current privilege lists for MDs identified revisions in their privileges since 1999 that were not reflected in the book in the OR. During an interview the Administrative Director of Surgical Services stated the standard was if the OR did not receive any updates, the old ones were still in effect. During an interview the Medical Staff Coordinator stated the OR should have requested new privilege files on the surgeons. Both stated the current system was flawed and MDS privilege lists in the OR were outdated and did not reflect their current scope of practice.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2)(A) and/or (4)(A) and/or (i) General (7).

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12. Based on review of the clinical record and interview, the facility failed to follow up on ordered lab work prior to discharging Patient #12. Staff failed to include a trocar as a piece of miscellaneous equipment that needed to be accounted for during surgery for Patient #3, and/or ensured that a trocar was removed during surgery and/or to assure the temperature for saline used for irrigation was not more than 100 degrees Farenheit, and to assure flash sterilization was not used or a routine basis. The findings include:
    a. Patient #3 underwent a laparosopic Roux en Y Gastric bypass and lysis of adhesions due to morbid obesity on 1/12/04. An operative note written on 1/12/04 at 3:30 p.m. identified the patient returned to the OR for a laparoscopic removal of an EEA trochar. The patient did well and was discharged on 1/16/04. During an interview MD #36 stated as PA #2 pulled the trocar out it caught on the end of the port and fell into the abdominal cavity. During an interview PA #2 stated she purposefully dropped it to reposition it to get it out of the abdomen and it rolled out of view. Due to the anastomosis being the most complicated portion of the surgery it was not possible to reposition any of the scopes and a decision was made to retrieve the trocar later. Both MD #36 and PA #2 stated they did not recognize they failed to retrieve the trocar until they were doing a subsequent case. The patient was returned to surgery and the trocar was retrieved without difficulty.
    b. Patient #12's diagnoses included chronic renal failure, which required hemodialysis, diabetes, history of myocardial infarction, and history of bleeding from operative sites. Review of the medical record identified that the patient underwent a creation of an AV fistula and exchange of a Perm-Cath on 10/17/03. The patient was admitted for observation due to soaked and bloody AV fistula dressings on 10/17/03. Further review of the medical record identified that the patient soaked through the AV fistula dressing site on 10/17/03 while in the recovery room, the patient's blood pressure dropped to 85/41(baseline was 103/45 to 153/98) and the patient had complaints of feeling shaky. The patient was treated with intravenous fluids. The labs dated 10/18/03 identified hemoglobin 9.2 (was 10.5 on 10/16/03) and hematocrit 27.9 (was 31.4 on 10/16/03). The surgeon, MD # 6, ordered a complete blood count (including hemoglobin and hematocrit) for 10/19/03. Review of the medical record lacked documentation that a complete blood count was done on 10/19/03. MD #6 discharged the patient on 10/19/03 without follow up of the ordered labs. Interview with MD #6 identified that he could not recall if he looked for a hemoglobin or hematocrit level prior to discharging the patient. MD #6 further identified that he was not concerned about the hemoglobin of 9.2 on 10/18/03 because the patient was a

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hemodialysis patient and the patient's hemoglobin was usually [illegible] was admitted on 10/20/03 with an acute myocardial infarction [illegible] hemoglobin of 7.6 and hematocrit 22.9. Interview with MD #5 identified that the low hemoglobin and hematocrit level upon admission may have contributed to the acute myocardial infarction, but the patient also had a cardiac history, kidney disease, and central nervous system disease which may have contributed.

c. Patient #3 underwent a laparosopic Roux en Y Gastric bypass and lysis of adhesions due to morbid obesity on 1/12/04. An operative note written on 1/12/04 at 3:30 p.m. identified the patient returned to the OR for a laparoscopic removal of an EEA trochar. A review of the Nursing Memorandum of Operation identified the surgical count for instruments did not apply. A review of the facility's sponge, sharp and instrument counts policy identified the trochar was not listed under miscellaneous as a count item. A review of the 2003 AORN (Association of Operating Room Nurses) standards identified under Counts: Recommended Practice, that miscellaneous items should be counted on all procedures and included any small items with a potential to be retained in a surgical wound.
During an interview the Administrative Director of Surgical Services stated at the time of the incident the retained piece was identified as an anvil which was not part of the instrument count, and subsequent to this incident the policy was revised to include the anvil. Subsequent to surveyor inquiry it was identified it was the trochar and not the anvil as previously identified that was left in the patient and the Administrative Director again revised the policy to reflect accounting for the trochar.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (4)(A) and/or (e) Nursing Service (1) and/or (i) General (7).

13. During a tour of the Surgical Suite fluid/blanket warmers lacked temperature monitoring documentation. The thermometer identified the temperature was 110 degrees. A review of the facility warming cabinets in the OR policy identified the temperature of warming cabinets used for irrigation fluids must not exceed 100 degrees Fahrenheit. During an interview the OR Patient Care Manager stated the temperature range should not be more than 100 degrees but there was no policy to do any daily monitoring of the temperatures in the warmers.

THE FOLLOWING VIOLATIONS O[illegible]E REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR C[illegible]ECTICUT GENERAL STATUTES WER[illegible]NTIFIED

14. During a tour of the Surgical Suite a[illegible] the flash sterilizer logs identified a frequency of usage. During an interv[illegible] the Administrative Director of Surgical Services stated the sterilizers were used on days when there were multiple eye cases done due to a lack of instruments to perform ten eye cases in succession without flash sterilization being done.

The above are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (e) Nursing Service (1) and or (i) General (7) and/or (l) Infection Control (4)(D).

15. Based on a review of the medical records, review of facility policy and procedure, and interviews, the facility failed to ensure a "minor" history and physical contained complete information.
    a. Patient #30 underwent a removal of an ano-rectal abscess in ambulatory surgery. A review of the "minor" history and physical identified an area for past history/family history which documented the patient's history only relative to the issue and lacked documentation of any family history, physical examination was documented with a drawing of the area, and lungs-clear.
    b. Patient #32 underwent placement of bilateral ear tubes for Chronic and acute otitis media in ambulatory surgery. A review of the minor history and physical identified the chief complaint, and a check list for present illness, past history/family history, physical examination, and disposition with a "yes" checked for each one but lacked any results. It also identified a type-written procedure of a myringotomy with insertion of tympanostomy tube(s) as the procedure on the sheet which was completed before surgery. A review of the Medical Staff Rules and Regulations identified a comprehensive history and physical examination shall be written or dictated within 24 hours of admission. A review of facility documentation identified a memorandum that the verbal directions from the Chief of Surgery directed that "all that is required from the surgeons was to document heart, lungs and site of surgery". A review of the Medical Staff Rules and Regulations failed to identify any information relative to this. During an interview the Administrative Director of Health Information Management (HIM) stated they followed what MD #35 directed and there were no policies in HIM or Surgery to support this, and there was a lack of consistency regarding the "minor" history and physicals done by various surgeons.

THE FOLLOWING VIOLATIONS OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED:

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (c) Medical Staff (2) and/or (d) Medical Records (3) and/or (i) General (7).

16. The facility failed to ensure that critically low oxygen saturation levels were communicated by the Anesthesiologist (MD #2) to the obstetrician and/or the obstetrician (MD #1) failed to immediately inform the Anesthesiologist (MD #2) of a concern regarding Patient #1's oxygenation upon exposure of the uterine cavity. In addition, CRNA #2 failed to communicate to the surgeon a change in vital signs prior to administering a second dose of narcotic medication to Patient #68. Also, staff failed to utilize medication to calm Patient #16 prior to initiating intravenous anesthesia. In addition, anesthesia consents were incomplete for Patients #3, #27, #28, #30, #31 and #32. The findings are based on clinical record reviews, staff interviews and review of policies and procedures and include the following:
    a. Patient #1 was admitted to the facility on 7/7/03 for elective induction of labor. Review of the clinical record identified that induction was unsuccessful therefore a cesarean section was performed. Interview with MD #3 identified that MD #2 stated monitoring equipment (pulse oximetry, EKG and B/P) was not applied to the patient until the spinal procedure was completed at 12:47 PM. MD #2 (Anesthesiologist) attached the patient to the monitoring equipment at 12:48 PM, the patient's O2 saturation dropped from 99% on 3 liters of oxygen to 90%. MD #2 failed to respond to the drop in O2 saturation and/or inform MD #1 (Obstetrician) of this value. In addition according to the hard copy monitoring strips the patients saturation dropped to 37% at 12:49 PM and 30% at 12:50 PM with no interventions implemented to address these critically low O2 saturation levels. There is no indication that MD #2 assessed and/or monitored the patient's level of consciousness at this time. In addition MD #2 failed to inform MD #1 (Obstetrician) prior to the start of surgery (12:51 PM) of these critical changes in O2 saturation levels (O2 SAT-30-37 %). Of note when comparing the anesthesia record with the hard copy monitoring sheets, MD #2 failed to record the critically low O2 saturation levels. Review of the OR record with MD #1 (Obstetrician) identified that at 12:50 PM the initial skin incision was made. On exposure of the uterine cavity (12:51 PM) MD #1 recalled seeing dark blood, however, he did not inform MD #2 of his observation. MD #1 stated that he made the decision to complete the delivery of the fetus. At 12:52 PM a viable infant was delivered (Two minutes later). MD #1 stated that the infant appeared to be depressed, which was not expected based on previous fetal tracings. Upon closure of the

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during induction MD #1 and PA #1 observed that the patient's blood was somewhat dark and questioned MD #2 as to whether the patient was oxygenating well. PA #1 stated that MD #2 responded, "yes." PA #1 further stated that within the next 15-30 seconds, MD #2 stated that there was a problem and that the patient was in asystole. At this time CPR was initiated and the patient was resuscitated. Review of the CPR flow chart identified that the patient was in asystole for approximately 5 to 6 minutes and sustained an anoxic brain injury with preserved brainstem function and no upper cortical function. Interviews with MD #1, RN #1, RN #2, PA #1 and the Scrub Technician stated that no alarms were audible during the spinal or surgical procedure that indicated the patient was in distress. MD #3 stated that a woman undergoing a C-section can de-saturate very quickly related to the hypermetabolic state of pregnancy, the position of the patient (supine) required for surgery along with fetal positioning which reduces respiratory reserve. In addition the relief of labor pain secondary to anesthesia also induces a relaxed state which contributes to decreased respiratory effort. MD #3 stated that the anesthesia record was not reliable in that monitoring equipment was not applied to Patient #1 by MD #2 prior to spinal anesthesia and MD #2 failed to detect hypoxemia at an earlier stage. Interview with MD #3 identified that he questioned the recorded vital signs and how the vital signs were determined if no monitoring equipment was in place. MD #2 failed to follow the hospital's policy for instituting monitoring equipment prior to the initiation of spinal anesthesia.

b. Patient #16 arrived at the facility on 2/9/04 for a scheduled endoscopy and colonoscopy. Review of the minor history identified diagnoses that included abdominal pain, anxiety and a history of asthma. Review of the ambulatory admission assessment identified that the patient was anxious and had stranger anxiety. Review of the Nursing Memorandum with RN #9 (Circulating Nurse) identified that the patient was very nervous prior to the procedure and was observed to cry and withdraw her arm while MD #12 (Anesthesiologist) attempted to insert an intravenous line required for the procedure. Review of the preanesthesia form with MD #12 and interview identified that the patient was extremely anxious and was fearful of receiving an Intravenous (IV) line. Interview identified that following 15 to 20 minutes of coaching, the patient allowed the IV to be inserted. Following the insertion of the IV, Versed (sedative) 1 mg IV was administered and the IV site noted to be infiltrated. MD #12 stated that when he explained the need to restart the IV, the patient

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became hysterical therefore a gas mask was placed over the patients face to achieve sedation. Interview with CRNA #1 identified that she observed the patient to be crying, restless, almost combative and assisted MD #12 to hold the patient while the gas mask was applied. Interview with MD #12 stated that Versed by mouth could have been used prior to the initiation of the IV to calm the patient but was not available. Interview with MD #3 stated that Versed was available orally as well as other medications that could have been utilized in an attempt to alleviate the patient's anxiety level.

c. Patient #68 was admitted to the facility on 4/16/04 for a scheduled inguinal hernia repair. Review of the Anesthesia Record dated 4/16/04 with CRNA #2 identified that the patient's weight was 10 kilograms, inhalation agents (Sevoflurane and Nitrous Oxide) were utilized to achieve sedation at approximately 7:45 AM and surgery started at 7:47 AM. The Anesthesia Record identified that Morphine 1.5 milligrams (mg) Intravenously (IV) was administered at 7:50 AM and 8:10 AM. Review of vital signs from 8:00 AM through 8:15 AM identified that respirations were documented as 20 breaths per minute and pulse rate was 120, 112, and 110 per minute respectively. Interview with CRNA #2 identified that the first dose of Morphine was administered to prevent post-operative pain and the second dose was administered when a fluctuation in vital signs (Respirations – 45 and Pulse 150-160) was observed although not noted in the medical record. There was no indication that CRNA #2 discussed the (undocumented) change in vital signs with the surgeon prior to administering the second dosage of morphine. Review of the medical record with MD #18 (Anesthesiologist) postoperatively identified that the patient had periods of oxygen de-saturations (to 72%) became somnolent, required four doses of Narcan (10:20 AM, 12:45 PM, 2:05 PM and 3:15 PM) and was transferred to another acute care facility at 7:00 PM for further evaluation. Review of the clinical record and interview with MD #16 (Pediatrician) identified that the patient received a significant overdose of Morphine intraoperatively.

d. A review of the Consent and Assignment for Anesthesia Services Form for Patients #3, #27, #28, #30, #31 and #32 identified documentation was lacking for either a date/time signed by the patient and/or physician, and/or the physician's signature, and or the identify of the person who explained the risks and benefits to the patient. A review of the facility's consent for treatment and diagnosis policy failed to identify any reference to the Anesthesia consent form. During an interview, the Administrative Director of Surgical Services

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stated the consents were incomplete, it was Anesthesia's responsibility to complete them, and the general consent policy of the facility applied.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2)(B) and/or (4)(A) and/or (d) Medical Records (3) and/or (i) General (7).

17. Based on record review and interviews, the hospital failed to ensure that organized physician's services were provided for 8 our of 8 sampled patients (Patients #2, #38, #39, #41, #47, #62, #62 and #64) seeking treatment for alcohol intoxication and/or detoxification were discharged from the emergency department without proper physician orders. The findings include:
    a. Eight (8) emergency department (ED) patient records with admitting diagnoses of acute alcohol intoxication and/or detoxification were reviewed. The eight patients had a total of eleven (11) admissions to the ED. In all 11 cases, there were no orders for discharge by a qualified practitioner. The patients and admission dates reviewed included Patient #2 with an admission date of 10/28/03, Patient #38 with an admission date of 2/18/04, Patient #39 with an admission date of 2/2/04, Patient #41 with admission dates of 10/25/03 and again on 10/28/03, Patient #47 with admission dates of 10/24/03 and 1/22/04, Patient #62 with admission dates of 10/20/03 and 4/28/04, Patient #63 with and admission date of 1/5/04, and Patient #64 with an admission date of 3/29/04. Hospital policy identified that only a physician or APRN can discharge a patient. Interview with the Quality Manager identified that in review of emergency department practices, patients with diagnoses of acute alcohol intoxication and/or detoxification were not always discharged by a qualified practitioner.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (j) Emergencies (2) and/or (i) General (7).

18. Based on review of hospital documentation and interviews, the hospital failed to keep current policies and procedures regarding abuse. The findings include:
    a. Hospital policies and procedures provided by the hospital during the investigation, related to child abuse and/or neglect within the pediatric and emergency departments, were reviewed. Although the hospital had policies and procedures geared towards identification of abuse, risk factors, reporting,

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evidence collection, and intervention, they had not been reviewed or revised since 2001. Interviews with the Executive Director for Ambulatory Care, who is responsible for the ED, and the Compliance Officer identified that it is the hospital expectation that the policies be reviewed on an annual basis. The Executive Director identified that policies are reviewed on a weekly basis with the ED team and that she recalled completing a signature face-sheet each year, however, was unable to produce that documentation.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (e) Nursing Service (1).

19. The facility failed to ensure that equipment functioned properly for one patient (Patient #69) and includes the following:
    a. Review of the clinical record identified that Patient #69 was maintained on a ventilator postoperatively. Review of RN #11's nurse's note dated 4/11/04 at 12:50 PM and interview with RN #11 identified that she observed the patient's ventilator tubing to disconnect from the Endotracheal Tube (ETT) site and stated that alarms did not sound because she quickly reattached the tube. Interview with Respiratory Therapist (RT) #2 identified he heard a low priority alarm sounding, entered the patient's room, assessed the ventilator to identify the rationale for the alarm to sound and when he looked over at the patient (approximately 20 seconds later), observed that the ventilator tube had detached from the ETT site. During an interview with RT #2 he stated he was unable to identify why the high priority alarm did not sound when the patient became disconnected from the ventilator. Subsequently, CPR was initiated and the patient was resuscitated. Interview with MD #31 identified immediately following the event, the ventilator screen had identified that a high priority alarms were noted to have sounded prior to this event but did not make note of the time in which they occurred. MD #31 further identified that when a ventilator detaches, a high priority alarm should sound.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administrator (2) and/or (i) General (7).

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20. Review of Patient #1's anesthesia record dated 7/8/03 identified that Duramorph (narcotic) 0.5 milligrams was administered to Patient #1 during the spinal procedure and 4.5 mg was destroyed. Interview with RN #1, RN #2 and MD #3 identified that hospital protocol for narcotic disposal was to co-sign the discard on the anesthesia record. Review of the anesthesia record failed to identify this procedure was followed.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Service (1).

21. Review of Patient #1's monitoring strips with the Manager of Bio-Medical Engineering dated 7/8/03 identified that the strip times were approximately 55 minutes behind the operating room clock time due to the daylight savings time change (4/6/03). Interview identified that although some equipment was changed to reflect the time change, no system was in place to ensure that the correct time of day is displayed on all equipment when daylight savings time occurs.

22. Review of facility documentation identified that on 4/19/04 a Service Recap was performed on a ventilator that was utilized for Patient #69. Review of the synopsis report identified that the time on the ventilator was off by one hour. Interview with the Manager for the ICU identified that the time discrepancy was related to daylight savings time and that Biomedical engineering was responsible to change the time on equipment when daylight savings occurs.

The above are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (a) Physical Plant (4) and/or (b) Administration (2) and/or (i) General (7).

23. Patient #11 had a nurse's note dated 11/16/03 at 1:45 PM that identified the Patient had coughed up large amounts of green bile, was dusky, diaphoretic and had an oxygen saturation of 50% on 2 liters of oxygen. The note identified that the patient received a respiratory treatment, aggressive suctioning and required 100% non-rebreather oxygen with the oxygen saturation increased to 92%. Interview with RN #12 identified that the gastrostomy tube was discovered to be clamped off by the stopcock and when unclamped, drained approximately 450 cc of green bile. Review of the nursing care record with RN #12 failed to identify that vital signs and/or respiratory assessments were documented following the above noted event. Interview with RN #12 stated that although respiratory assessments were conducted and vital signs monitored, she failed to document this information in the clinical record.

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The above is a violation of the Regulations Connecticut State Agencies Section 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Service (1).

24. Review of the medical record identified that Patient #40 underwent a Transesophageal Echocardiogram (TEE) on 4/9/04 at 8:30 AM. Review of the intraprocedure form with the Director of Medicine identified that the TEE was completed at 9:30 AM. According to the procedure form utilized, vital signs (B/P, Pulse, Respiration's, oxygen saturation) were assessed at 9:40 AM and 9:45 AM then the patient was transferred to the department of nuclear medicine. Review of the moderate sedation policy identified that discharge criteria included stable vital signs for at least 30 minutes and Temperature within 1 to 2 degrees of the patient's admission Temperature. Review of the medical record lacked documentation that vital signs were assessed for thirty minutes and/or that the patient's temperature was assessed in accordance with facility [illegible].

25. Review of the moderate sedation policy identified that a patient who has received conscious sedation would be assessed utilizing the Aldrete score to determine when discharge criteria are met. Review of the Post Anesthetic Recovery Score (Aldrete score) for Patient #40 dated 4/9/04 with the Director of Medicine identified although blood pressures were documented at 9:40 and 9:45 AM, the Aldrete score was incomplete prior to the patient's discharge to another department. Additionally, assessment criteria used to determine patient's color following sedation differed when compared to the sedation policy. The procedure form identified color would be assessed as 0 (zero) for normal; 1 (one) for pale/dusky/blotchy and 2 (two) for color/appearance (typo on procedure form). The moderate sedation policy identified: 0 (zero) for cyanotic; 1 (one) or pale/dusky/blotchy and 2 (two) for normal color/appearance.
Review of the TEE procedure form dated 4/9/04 utilized for Patient #40 lacked a date and/or time and/or signature of the person who completed the discharge assessment.

26. Patient #68 was admitted to the facility on 4/16/04 for a planned right inguinal hernia repair. Review of the Pre-Anesthesia evaluation with CRNA #2 failed to identify that vital signs (Temperature, Heart Rate, Blood Pressure and /or Respiratory rate) were recorded.

27. Review of Patient #68's Pre-Anesthesia Record with MD #18 (Anesthesiologist) identified that the patient had not consumed any liquids by mouth since 4/15/04 at 11:00 PM. Review of the Anesthesia record identified that Intravenous solution (Dextrose/Normal Saline) was administered intraoperatively but failed to document the

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amount of IV solution that was consumed. Interview with MD #18 identified that the amount consumed should be reflected in the record.

28. Patient #68 was transferred to the Post Anesthesia Care Unit (PACU) on 4/16/04 at 8:29 AM. Review of the PACU record reflected that B/P assessments were conducted at 9:45 AM, 10:00 AM, 10:15 AM and 10:30 AM. Nurse's note at 10:15 AM identified a change in the patient's condition (oxygen saturation 90-91%, heart rate to 160 beats per minute from 130, mental status change) and required Narcan. Subsequently the patient was transferred to the pediatric unit at 11:20 AM. Review of the PACU record identified that Post Anesthesia scores would include B/P assessments upon admission to the unit then in fifteen-minutes, thirty-minutes, one-hour and upon discharge. Review of the Discharge policy identified that B/P assessments were required to determine the minimum post anesthesia recovery score (based on the Aldrete scoring system) and directs when the patient can be discharged from the PACU. Review of the PACU record failed to identify that B/P assessments were conducted upon admission, during the 15 and 30 minute time frame and upon discharge in accordance with facility policy.

29. Review of Patient #15's medical record identified three transfusions for fresh frozen plasma dated 4/20/03 lacked documentation of the time completed. Review of the Administration of Blood, Platelets, and Fresh Frozen Plasma Policy directs that the registered nurse will document the time completed.

The above are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (3) and/or (f) Diagnostic and therapeutic facilities and/or (i) General (7).

30. Patient #5's diagnoses included atrial fibrillation, pneumonia, and a left humeral fracture. Review of the clinical record identified that Patient #5 attempted to climb out of bed on 11/3/03 at 5:00 a.m. and was found on the floor on 11/4/03 at 10:30 a.m. Although nurses' notes dated 11/4/03 and 11/5/03 identified the use of four siderails, the clinical record lacked a physician's order and/or documentation that the patient was assessed while the siderails were being used. The 7th floor Resource Manager stated that when four siderails are utilized on the new beds, they are not considered restraints because the patient can climb out between the rails and at the foot of the bed. According to the facility restraint policy, two to three siderails are not considered a restraint and do not require a physician's order; however, restraints require a physician's order which will be renewed every twenty-four hours. In addition, patients will be observed every hour and observations are documented on the "Restraint Flow Sheet". Review of the fall protocol

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and the restraint policy with the Director of [illegible]nagement identified that when a patient is assessed at low risk to fall, three to [illegible] siderails are used. The Director of Quality Management stated that the two policies conflict with one another and the fall protocol should read "one to three siderails."

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Service (1).

31. Patient #6 had a history of COPD, asthma, oxygen dependency, hypertension, CHF, GERD, depression, right ankle fracture and was admitted to the facility on 11/11/03 with pneumonia and a urinary tract infection. A review of the medical record identified restraints were initiated based on a physician restraint order dated 11/13/03 because the patient removed her oxygen, desaturated, and became agitated and combative. The restraint was ordered for two hours beginning at 6:00 a.m. The restraint order lacked documentation of any alternative interventions tried, explanation given to the patient or family, and criteria to discontinue the restraint. A review of the decision map for agitated and confused patients identified it was blank. Progress notes written on 11/13/03 at 7:00 a.m. identified the patient was alert but confused, kept removing her oxygen mask and desaturated, and wrist restraints were applied to prevent her from taking the oxygen off. A review of the medical record failed to identify any documentation for restraint monitoring or when the restraints were discontinued. A review of the facility restraint policies identified the decision map must be completed, and signed by the RN, Patient Care Manager or Clinical Nurse Manager in order to assure alternative measures prior to restraint were reviewed and restraint need verified by using the decision map, an explanation given to the patient or family, and criteria for discontinuation of restraints identified. The patient must be observed every hour, and care given will be document on the restraint flow sheet every two hours. During an interview RN #22 stated he completed the flow sheet, however the facility was unable to locate the restraint flow sheet. During an interview the Patient Care Manager 7 West stated the restraint should not have been applied until the clinical manager assessed the need, the decision map completed, and alternatives such as a sitter tried.

32. A review of Patient #6's medical record identified progress notes written at 7:00 a.m. documented when restraints were applied due to the patient's agitation from hypoxia on 11/13/04, multiple skin tears were noted with some bleeding on the right arm, and tegaderm, kerlix and gauze were applied to the areas. Progress notes written on 11/13/04 at 9:15 a.m. identified the patient's right hand had a 3cm by 6 cm and a 2.5cm by 4.5cm

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skin tear on the anterior surface of the hand and a 2cm by 1 cm tear on the right third digit. A consultation by MD # 38 identified the patient sustained a degloving injury to the right forearm and hand and required sutures. During an interview RN #22 stated the patient removed her oxygen mask, became hypoxic, got agitated and confused, and would not keep the mask on. The patient kicked, screamed, and scratched him and restraints applied. The patient's oxygenation improved as a result of keeping her mask on. RN #22 applied gauze and dressings to the skin tears before the wrist restraints were applied. During an interview PCT #1 stated the patient was all over the bed, turning blue, pulled her IV out, the site bled, had several old skin tears on both arms and hands and bandages on her arms also. Despite RN #22's attempts to calm the patient, she became agitated, scratched and kicked RN #22, and once restrained with her oxygen on, calmed down. Both RN #22 and PCT #1 stated they were not aware of any new injuries only that because she was fighting so much and moving around, she re-opened old tears. During an interview, the Patient Care Manager 7 West stated the act of placing the patient in restraints was not in her best interest and the injury occurred due to the patient's agitation.

The above are violations of Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical records (3) and/or (e) Nursing service (1) and/or (i) General (7).

33. During a tour of the ambulatory surgical unit MD #32 was observed inserting an IV without any gloves on and upon completion of the insertion failed to perform handwashing. A review of the facility's Barrier Protection and Isolation policy identified prevention was the goal of Barrier Protection which should be used when a procedure performed involves body fluid likely to come in direct contact with skin or mucous membranes of a provider in order to decrease the risk of infection. During an interview MD #32 stated he doesn't wear gloves when he starts IV's and forgot to wash his hands.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (i) General (7) and/or (l) Infection Control (1).

34. Based on review of hospital documentation and interviews, the hospital's emergency department failed to keep current and/or enforce policies and procedures regarding EMTALA regulations and emergency services. The findings include:
    a. Review of the ED policy and procedure manual during the April 2004 visits identified that emergency services policies and procedures relevant to EMTALA regulations had not been reviewed or revised since 2001. The

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policies included assessment and reassessment and care of the psychiatric patient. Interviews with the Executive Director for Ambulatory Care, who is responsible for the ED, and the Compliance Officer identified that it is the hospital expectation that the policies be reviewed on an annual basis. The Executive Director identified that policies are reviewed on a weekly basis with the ED team and that she recalled completing a signature face-sheet each year, however, was unable to produce that documentation.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (j) Emergencies (2) and/or (i) General (7).

35. Based on record review and interviews, the hospital failed to ensure that an appropriate medical screening examination by qualified individuals was provided for 7 out of 7 sampled patients seeking treatment for alcohol intoxication and/or detoxification and psychiatric services. The findings include:
    a. Patient #2 was brought to the hospital by ambulance on 10/28/03 at 12:05 PM for complaints of suicidal ideations and palpitations. MD #21, an attending physician in the emergency department, examined the patient and identified the patient had a blood alcohol level of 264 and had taken several Doxepin tablets. The patient had a history of prior suicide attempts and stated "I need help." Following laboratory blood work and an EKG, the patient was medically cleared by MD #21 and a psychiatry consult was requested. Patient #2 was placed in the psychiatric holding area, was seen by psychiatric RN #15 who identified to hold the patient until the AM, pending possible placement at an alcohol treatment/rehabilitation facility. Patient #2 was seen again on 10/29/03 at 9:30 AM by RN #15, who documented that the patient had no current suicidal ideations, no psychosis, and his behavior was appropriate. When no beds were available at a treatment center, the patient was given a taxi token and train fare to travel to New Haven in search of a bed at another treatment/residential center. Patient #2 was given discharge instructions to attend an appointment at a treatment center on 11/3/03, stop drinking alcohol, and to attend an alcohol program. The patient was not seen by a physician or psychiatrist prior to being discharged on 10/29/03 at 10 AM by RN #15. Patient #2 was returned to the hospital on 10/29/03 at 5: 30 PM by ambulance following a suicide attempt by hanging. The patient was in asystole, resusitation efforts failed, and the patient was pronounced dead at 6:05 PM. Review of hospital policy and procedures identified that only a physician or APRN can discharge a patient and when psychiatry services are requested in the

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emergency department, central intake clinic consisting of psychiatric RN's or LCSW's, assess the patient and make an initial determination and referral to an appropriate level of care. Then, the on-call psychiatrist or APRN are contacted to continue the evaluation process. Interview with RN #15 identified that she did not routinely involve a psychiatrist in cases where patients are treated for alcohol intoxication and/or detoxification. RN #15 stated that she was aware of the hospital policy requiring contacting a psychiatrist and that she should have contacted the psychiatrist. RN #15 stated that she did not contact the psychiatrist or the ED physician about her determination that the patient was safe to be discharged, or about the discharge plan she developed, or to obtain a discharge order. RN #15 stated she did not feel that she discharged the patient. Interview with MD #21 identified that he took Patient #2's complaint of suicidal ideations very seriously when the patient arrived at the ED on 10/28/03. MD #21 requested the psychiatric evaluation with the expectation that the intake staff would bring their information to a psychiatrist. MD #21 stated he did not provide care for Patient #2 after 10/28/03 and was not the one who placed a check-mark in the box indicating the disposition of "discharge." Interview with the Administrative Director of Quality Management identified that the hospital staff were unable to determine who placed a check mark in the patient's record that indicated "discharge."

b. Patient #47 presented to the ED intoxicated and requesting detoxification. The patient was assessed by the psychiatric LCSW in the ED on 1/22/04 who identified that the patient's health insurance would not authorize a stay. The patient was offered a referral to an alcohol rehabilitation facility, which he refused. The patient requested to be discharged and was discharged by the LCSW to a shelter with a plan for the patient to contact the rehabilitation facility tomorrow. Nursing notes identified that Patient #47 was discharged home by the LCSW at 11 AM on 1/22/04. Patient #47 returned to the ED on 1/23/04 intoxicated and with a blood alcohol level of 311. Psychiatric services were requested, the patient was seen by the LCSW, and transferred to an alcohol rehabilitation center. The psychiatrist was not consulted regarding the patient's plan for transfer, as per hospital policy. Interview with the LCSW identified that she did not consult with the psychiatrist in either of Patient #47's ED admissions. The LCSW identified that the hospital practice at that time was to only consult with a psychiatrist regarding their assessments and plan for discharge when patients were suicidal, psychotic, or exhibited other psychiatric issues. The

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LCSW stated that she would discuss a patient's plan of care and discharge with the ED physicians but did not document those discussions.

c. Five (5) additional patients were admitted to the ED and identified as utilizing psychiatric services. In all cases, the psychiatrist was not consulted regarding the RN or LCSW's assessment and discharge plans. Patient #39 with an admission date of 2/2/04, Patient #41 with admission dates of 10/25/03 and again on 10/28/03, Patient #62 with and admission date of 10/20/03, Patient #63 with and admission date of 1/5/04, and Patient #64 with an admission date of 3/29/04.

The above are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (e) Nursing Service (1) and/or (i) General (7) and/or (j) Emergencies (2).

36. Patient #71 had diagnosis that included endocarditis, pancreatitis, and Hepatitis B and C. Review of the medical record identified that the patient was scheduled for a Transesophageal Echocardiogram (TEE) with conscious (moderate) sedation on 4/19/04. Review of the facility's policies for pre-procedure assessments of patients who undergo moderate sedation included that a classification in accordance with the American Society of Anesthesiologist (ASA) Classification utilized to identify any systemic disturbances a patient may have that might affect the patient response to the procedure. Review of the medical record lacked documentation to reflect that a physician assigned an ASA classification category to Patient #71 prior to the procedure. Interview with the Director of Radiology on 4/8/04 identified that a patient with liver disease would have more difficulty clearing medications administered during a procedure. In addition, a review of the conscious sedation documentation form identified specific discharge criteria to be addressed pose procedure by the physician that included the disposition of the patient, return to baseline information, and absence of respiratory distress. Although the physician signed the discharge assessment form, the form lacked documentation of a date or time of the physician's assessment or that Patient #71 met the discharge criteria.

The above is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (3) and/or (i) General (7).